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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/756,690	01/09/2001	Orville G. Kolterman	030639.0066.UTL	4666

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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 12/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/756,690	KOLTERMAN ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15,24-37 and 41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15,24-37 and 41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

In view of the decision of the pre-appeal brief conference based on applicants Pre-Appeal Brief Request filed on 15 August 2006, PROSECUTION IS HEREBY REOPENED. The finality of the rejection of the last Office action is withdrawn.

Currently, claims 1-15 and 24-37 and 41 are pending and under consideration.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-14, 24-36 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Beeley et al. (WO 98/30231), and Karpe et al. (Metabolism, 1999, 48:301-307), for the reasons of record set forth in the previous Office Actions, and for the reasons below.

The teachings of Karpe and Beeley were reviewed in the previous Office Actions.

Briefly, Karpe discloses that the postprandial elevation of plasma triglycerides is more closely linked to the risk of developing coronary heart disease (CHD) than the fasting level, and that the plasma triglyceride concentration measured 6 hours after a mixed meal was associated with signs of early atherosclerosis in healthy men (page 301, the second paragraph of the left

column; and page 306, the last paragraph of the right column). Karpe does not teach a method for lowering triglyceride levels with an exendin.

Beeley teaches a method of treatment by administering an exendin or an agonist thereof, and indicates that the method is useful for, among others, reducing the cardiac risk (abstract, and page 10, lines 16-19). Additionally, Beeley teaches that the method is also useful for reducing appetite (food intake), reducing the weight of subjects, and lowering plasma lipid levels (abstract, page 1, lines 18-24, and page 10, lines 6-15), which comprise cholesterol and triglycerides.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to identify and to treat a subject having elevated postprandial triglyceride levels by administering an exendin or an agonist thereof following the method taught by Beeley in order to reduce the cardiac risk, as Karpe indicates that the postprandial elevation of plasma triglycerides is more closely linked to the risk of CHD. The person of ordinary skill in the art would have been motivated to do so in order to treat and reduce the risk of CHD, and reasonably would have expected success because Beeley has taught that exedin can reduce the cardiac risk, and that exedin can lower plasma lipids, and control obesity (by reduce food intake), which are well known and important risk factors for in cardiovascular diseases.

While such a treatment is implemented to a subject identified as one at the cardiac risk because of elevated postprandial triglyceride levels, it would be inherent that said subject's postprandial plasma triglyceride levels would be lowered, as the active ingredient and method steps would be the same as that of the present invention.

Applicants argument, filed on 15 August 2006 has been fully considered, but is not deemed persuasive for reasons below.

At page 2 of the response, the applicant argues that the examiner is wrong as a matter of law as obviousness cannot be predicted on what is unknown, and that there is no motivation to combine Karpe with Beeley and Beers because the inherent properties alleged by the examiner, even if they were true, cannot be used since that which is inherent cannot be combined. Applicants further argue, at page 3 of the response, that the examiner has failed to provide a basis in fact or technical reasoning to establish the inherent characteristic relied on, and that to be

found inherent in an anticipating reference, an unstated element must exist as a matter of scientific fact and flow naturally from the elements expressly disclosed in the prior art reference. This argument is not persuasive for the following reasons. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Beeley teaches a method of treatment comprising administration of an effective amount of an exendin or an exendin agonist, and indicates that the method is useful for, among others, lowering the plasma lipid level, reducing the cardiac risk (abstract, and page 10, lines 12-19). Therefore, it would be obvious to include cardiac risk patients in Beeley's method of treatment. Karpe teaches how to identify subjects with the cardiac risk, wherein the postprandial elevation of plasma triglycerides is more closely linked to coronary heart disease (CHD) than the fasting level, and that the plasma triglyceride concentration measured 6 hours after a mixed meal was associated with signs of early atherosclerosis in healthy men (page 301, the second paragraph of the left column; and page 306, the last paragraph of the right column). Therefore, it would be obvious to first identify subjects at the cardiac risk following the teachings of Karpe, i.e., those with elevated postprandial plasma triglyceride levels, and then to treat such subjects by administering an exendin or an agonist thereof to reduce the cardiac risk as taught by Beeley. The person of ordinary skill in the art would have been motivated to do so in order to reduce the cardiac risk. Once an exendin or an agonist thereof is administered to the identified subject at the cardiac risk (with elevated postprandial plasma triglyceride levels), it would be inherent that said subject's postprandial plasma triglyceride levels would be lowered, as the active ingredient and method steps would be the same as that of the present invention. As such, the unstated element (lowering plasma triglyceride levels) indeed exists as a matter of scientific fact and flow naturally from the elements expressly disclosed in the prior art reference.

At pages 3-4 of the response, the applicant argues that the examiner ignores identifying a subject having elevated postprandial triglyucerideds to administer an exendin or exendin agonist;

that Beerley does not teach or suggest the identification of a subjust having elevated postprandial triglyucerideds and the ability of exendins to specifically lower triglycerides; and that Karpe does not teach a method for lower triglyceride levels with an exendin. This argument is not persuasive for the reasons of record, and for the reasons above.

Claims 15 and 37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Karpe et al. (Metabolism, 1999, 48:301-307), and Beeley et al. (WO 98/30231), as applied to claims 1-14, 24-36 and 41 above, and further in view of Wagle et al., US 6,326,396 B1, for the reasons of record set forth in the previous Office Actions mailed on 11/17/04, 6/6/05 and 3/15/06, and for the reasons above.

Conclusion:

No claim is allowed.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
12/6/06

GARY B. NICKOL, PH.D.
SUPERVISORY PATENT EXAMINER
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